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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,079	10/13/2000	Robert E. Herman	F-5076-DIV	8404

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MICHAEL MAYO, ESQ.
BAXTER HEALTHCARE CORPORATIONL
FENWAL DIVISION P.O. BOX 490
ROUTE 120 AND WILSON ROAD
ROUND LAKE, IL 60073

EXAMINER	
PONNALURI, PADMASHRI	
ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/688,079	HERMAN ET AL.	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-43,62 and 70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-43,62 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/13/00* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/23/03 has been entered.

2. Claim 38 has been amended by the amendment filed on 10/23/03.

3. Claims 38-43, 62 and 70 are currently being examined in this application.

Drawings

4. In view of applicant's response, that the drawings corrections were made to correct the typographic errors, the proposed drawing corrections and formal drawings filed on 10/13/00 have been considered and entered into the application.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 38-43, 62, 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant amended claim recites 'an overwrap ... that absorbs light that activates the

photoactive material, thereby preventing degradation of the photoactive material prior to use.' it is not clear what does applicants mean by reciting overwrap that envelops the light filtering material that absorb the light that activates the photoactive material, thereby preventing the degradation of the photoactive material. If the ovewrap envelops the photoactive material, how does photoactive material is being activated. Applicants are requested to clarify.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 38-43, 62, 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,319,662 B1 (FOLEY et al).

The instant claims briefly recite a kit comprising a tubing, a transfer container, photoactive material, and an overlap enveloping at least a portion of the kit.
NOTE the instant claim 38 is amended to include the limitation 'thereby preventing degradation of the photoactive material prior to use', which is considered as inherent property of the component of the apparatus or the kit. . The instant claim is drawn to a kit, which has different components, the intended use or prior to use properties are not considered as patentable limitations.

Foley et al teach a method and apparatus for treating a body fluid to at least substantially inactivate viral contaminants that may be present therein. The reference in figure 1, discloses a container 10 (refers to the transfer container of the instant claims) including the blood component, and the blood component is added to the viral inactivating agent 13 (refers to photo activating material of the instant claims). The reference teaches that the viral inactivating agent can be methylene blue (i.e., see column 4) (refers to instant claim 39) or psoralen (i.e., see column 2, line 67) (refers to instant claim 42). The reference teaches that the container 10 will include a fluid line 12 (refers to the tubing of the instant claims) that will be coupled to a column (e.g., see column 4, lines 42-43). The figure 1 of the reference teaches that the system which has a container (10), in which the container walls would refer to the overwrap of the instant claims. The reference teaches that container 10 containing the blood component and the viral inactivation agent is activated by light of appropriate wavelength. Thus the walls of the container of the reference system absorb light, which clearly reads on the instant claim overwrap , which is 'enveloping at least a portion of the kit and including light filtering material that absorbs light

that activates photoactive material.' The reference container walls have similar properties (e.g., light filtering material which activates photoactive material) as the instant claim overwrap.

The reference teaches that the after the container containing the blood product and viral inactivating agent is activated by light of an appropriate wavelength, the resultant product flows through fluid line 12 into the affinity column 14. The affinity column 14 will remove excess viral inactivating agents as well as photo products (i.e., see column 4, lines 58-63). The reference teaches that the viral inactivating agents are chosen from the group; porphyrin, psoralens, phthalocyanines (refers to the instant claim 41). The reference in example 3 teaches the method of treating blood component with methylene blue and photo activating the blood component and filtering the product to remove the remaining photo activating agents.

The claimed invention differs from the prior art teachings by reciting a kit; and a kit comprising a first filtration media and second filtration media; and fist and second blood cellular species.

However, based on the reference disclosure of apparatus, it would be obvious to one skilled in the art at the time of the invention to group all the components of the apparatus used in the method in a kit for ease of use, such that the components can be packed together enables one skilled in the art to assemble them together to use anytime. The reference does not recite two different filtration media to eliminate two different species of blood components. However, the reference teaches that the irradiated blood components are passed through different types of filters to remove the excess viral inactivating agent and photo products. Thus it would have been obvious to one skilled in the art at the time the invention was made to use different filters to remove different components, such that selected blood components are obtained.

10. Claims 38-43, 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,300,019 (BISCHOF et al) and US Patent 6,319,662 B1 (FOLEY et al).

Bischof et al teach a system and methods for eradicating contaminants using photo active materials in fluids like blood. The reference teaches that the device includes an outer wall that defines the interior area. The outer wall is transparent to radiation within a prescribed wavelength to thereby pass the radiation into the interior area. The treatment chamber is formed in the interior area for receiving the fluid be treated, and the fluid carries one or more contaminants to which a photo activating agent is bound. The reference teaches that a single source of radiation is positioned outside the housing. The system envelops both the housing and source with a reflective surface that focuses radiation from the source or sources into the housing (see column 2). The reference figure 1 shows a system 10 for treating fluid carrying a contaminant. The system includes a treatment device 12 that receives fluid from a source container 14 and conveys after the fluid treatment to a collection chamber 16. The fluid in the source container 14 includes a photo active material that has an affinity for biological contaminant carried by the fluid. The treatment device 12 includes a housing 18 (refers to the overlap of the instant claims) that defines a treatment chamber 20.the housing wall 22 is made from a material that is essentially transparent to the radiation to thereby pass the radiation into the accurate gap 26. The radiation chamber 50 includes single source of radiation 52 and a reflector that envelops both the radiation source 52 and treatment device 12. The reference in figure 14 shows the treatment chamber, which includes a inlet 30 to the treatment device 12

includes the length of flexible inert plastic tubing 34. The tubing 34 includes a conventional filter 100 for removing the white blood cells from the fluid prior to entering the treatment device.

The reference does not recite different photo activating reagents such as psoralen, methylene blue and phthalocyanine. However, Foley et al teaches that the viral inactivating agents are chosen from the group; porphyrin, psoralens, phthalocyanines and methylene blue.

Foley et al teach a method and apparatus for treating a body fluid to at least substantially inactivate viral contaminants that may be present therein. The reference in figure 1, discloses a container 10 (refers to the transfer container of the instant claims) including the blood component, and the blood component is added to the viral inactivating agent 13 (refers to photo activating material of the instant claims). The reference teaches that the viral inactivating agent can be methylene blue (i.e., see column 4) (refers to instant claim 39) or psoralen (i.e., see column 2, line 67) (refers to instant claim 42). The reference teaches that the container 10 will include a fluid line 12 (refers to the tubing of the instant claims) that will be coupled to a column (e.g., see column 4, lines 42-43). The figure 1 of the reference teaches that the system which has a container (10), in which the container walls would refer to the overwrap of the instant claims. The reference teaches that container 10 containing the blood component and the viral inactivation agent is activated by light of appropriate wavelength. Thus the walls of the container of the reference system absorb light, which clearly reads on the instant claim overwrap, which is 'enveloping at least a portion of the kit and including light filtering material that absorbs light that activates photoactive material.' The reference teaches that the after the container containing the blood product and viral inactivating agent is activated by light of an appropriate wavelength, the resultant product flows through fluid line 12 into the affinity column 14. The affinity column

14 will remove excess viral inactivating agents as well as photo products (i.e., see column 4, lines 58-63). The reference teaches that the viral inactivating agents are chosen from the group; porphyrin, psoralens, phthalocyanines (refers to the instant claim 41). The reference in example 3 teaches the method of treating blood component with methylene blue and photo activating the blood component and filtering the product to remove the remaining photo activating agents.

The claimed invention differs from the combined teachings of references Bischof et al and Foley et al by reciting a kit. However, based on the reference disclosure of apparatus, it would have been obvious to one skilled in the art at the time of the invention was made to group all the components of the apparatus used in the method in a kit for ease of use, such that the components can be packed together enables one skilled in the art to assemble them together to use anytime. And further a person skilled in the art would have been motivated to combine all the components of the system taught by Foley and Bischof and pack them in a sterile envelop or cover such that the components are together until the time of the use.

Response to Arguments

11. Applicant's arguments regarding the art rejections (Foley et al or Bischof and Foley et al) filed on 10/23/03 have been fully considered but they are not persuasive.

Applicants argue that the new limitation 'thereby preventing degradation of the photoactive material prior to use' was added to the claims. Applicants argue that if the walls of the container (10) of Foley et al absorb light that activates the photoactive material, then the light would not reach the photoactive material and photo activation would not occur. Applicant's arguments have been fully considered and are not persuasive, since the reference

teaches that the container 10 containing the blood component and viral inactivation agent is activated by light that is the light has to pass through the walls of the container. Thus it is not clear what does applicant mean by 'if the walls absorb the light and activates the photoactive material, then the light would not reach the photoactive material and photo activation will not occur.' And applicant's correctly points out that 'the exact opposite occurs in Foley: the walls do not absorb light but allow the light to pass and reach the photoactive material, so that photo activation occurs.' If applicants mean that the ovewrap is different from the walls of the container, applicants are requested to point out specifically that the overwrap is a part of the system, not the container walls. And even if applicants mean that the overwrap is different , it would have been obvious to one skilled in the art at the time the invention was made to combine all the components of the system and pack them in a sterile envelop or cover such that the components are together until the time of the use. Thus the rejections of record have been maintained for the reasons of record.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 703-305-3884. The examiner is on Flex Schedule and can normally reached from Monday through Friday between 7.30 AM and 4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

Pp
16 January 2004